Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0895075	05/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Vega Alta Community Health	Carretera Numero 2, Km 31'9, Vega Alta, PR	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on quality assessment procedure manual, quality assessment records review (2017-2019) and laboratory director interview on May 8,2019 at 9:20 A.M. it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for pre analytic laboratory systems: test request. The findings include: a. Review of the quality assessment procedure manual showed that evaluations to test requisitions must perform each 3 months. b. Review of the quality assessment records showed that the laboratory did not evaluate the test requisitions in year 2018. c. The laboratory director confirmed on May 8, 2019 at 9:20 A.M. that evaluations to test requisitions were not performed in year 2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on manufacturer's written procedures, routine chemistry preventive maintenance records review (2018-2019) and laboratory general supervisor and

	laboratory director interview on May 8, 2019 at 9:45 A.M., it was determined that the laboratory failed to follow written instructions for the preventive maintenance of routine chemistry systems. The findings include: 1. The laboratory uses the Konelab and Easy Lyte system to perform routine chemistry tests. 2. The manufacturer's written procedures establishes that the laboratory must document and perform the daily, weekly and monthly preventive maintenance. 3. Review of Kone Lab system preventive maintenance records from January 2018 to May 2019 , showed that the laboratory did not perform nor document the weekly preventive maintenance (wash dionised and wastewater container, wipe off condensing water under reagent disk) and the monthly preventive maintenance (wash tubes with diluted washing solution 4.5%). 4. Review of Easy Lyte system preventive maintenance records from January 2018 to May 2019 , showed that the laboratory did not perform nor document since March 2018 the biannual preventive maintenance (membrane change, change pump sleeve, change fill filling solution, sample sleeve change. 4. The laboratory processed and reported 39,473 routine chemistry patient samples on 2018. 5. The laboratory director confirmed on May 8, 2019 at 9:45 A.M that the laboratory failed to follow written instructions for the preventive maintenance of routine chemistry systems.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of hematology statistical parameters , hematology quality control review and interview with the laboratory director and the laboratory general supervisor on May 8, 2019 at 10:45 A.M., it was determined that the laboratory did not evaluate nor define the statistical values of quality control material used by the Sysmex KX-21N instrument from September 1, 2018 to September 23, 2018 and from November 22, 2018 to November 29, 2018. The findings include: 1. The laboratory use the Sysmex KX-21N to perform hematology tests. 2. The laboratory did not have any statistical data (Levy-Jennings, control value mean and limits) of the control materials used from September 1, 2018 to September 23, 2018 and from November 22, 2018 to November 29, 2018. 3. The laboratory general supervisor stated on May 8, 2019 at 10:45 A.M.that the laboratory lost the quality control data due a problem with the system on September 2018. The laboratory retain the quality control print out, however, did not evaluate the controls value in Levy Jennings graphs. 4. The laboratory performed 559 hematology patient samples during those days. 5. The laboratory director confirmed on May 8, 2019 at 11:00 A.M , that the laboratory failed to evaluated the statistical data of the quality control material used during those days.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review (2017-2019), laboratory director and laboratory general supervisor interview on May 8, 2019 at 11:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment records showed that the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic system. Refer to D 5429 and D 5469. 3. The laboratory director confirmed on ay 8, 2019 at 11:00 A.M., that the laboratory failed to evaluate aspects regarding the analytic system.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on hematology and routine chemistry records review (2017-2019) and interview with the laboratory director on May 8, 2019 at 11:30 A.M. , it was found that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to follow written instructions for the preventive maintenance of routine chemistry systems. Refer to D 5429. 2. The laboratory did not evaluate nor define the statistical values of quality control material used by the Sysmex KX-21N instrument from September 1, 2018 to September 23, 2018 and from November 22, 2018 to November 29, 2018. Refer to D 5469.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on hematology and routine chemistry records review (2017-2019) and interview with the laboratory director on May 8, 2019 at 11:30 A.M. , it was found that the laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to follow written instructions for the preventive maintenance of routine chemistry

	systems. Refer to D 5429. 2. The laboratory did not evaluate nor define the statistical values of quality control material used by the Sysmex KX-21N instrument from September 1, 2018 to September 23, 2018 and from November 22, 2018 to November 29, 2018. Refer to D 5469.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on routine chemistry records review (2017-2019) and interview with the laboratory director on May 8, 2019 at 11:30 A.M. , it was found that the laboratory testing personnel failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory testing personnel failed to follow written instructions for the preventive maintenance of routine chemistry systems. Refer to D 5429.